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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,629	01/11/2000	HARALD SEULBERGER	48141	5335

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WASHINGTON, DC 20036

EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/462,629

Applicant(s)

SEULBERGER ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed 14 February 2004.
2. The Application is now in compliance with the Sequence Rules in view of the Amendment filed 22 July 2002.
3. The information disclosure statement filed 28 October 2002 fails to comply with 37 CFR § 1.98(a)(2), which requires a legible copy of each foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.
4. The drawings were received on 14 February 2002. These drawings are acceptable, and have been approved by the Draftsman.
5. The certified translation of the foreign priority document filed 26 February 2002 has been entered into the file. The translation, and Applicant's arguments have overcome the rejection under 35 USC § 102(b) in view of *Krupinska et al.*
6. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments to the claims.
7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

8. Claims 1, 2, 5, 14, 15 and 25 are objected to because of the following informalities: The limitation "sequence" after "DNA" should be deleted from the instant

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claims because "sequence" is information and not a composition of matter. Appropriate correction is required.

9. Claims 3-5 are objected to because "An expression" should read -- The expression -- because said claims refer claim 2. This objection replaces the rejection under 35 USC § 112, second paragraph, of the previous Office action.

10. Claim 5 is objected to under 37 CFR § 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

11. At claim 8 1), "agrobacterial" should be -- *Agrobacterium* --. In claim 8, the substeps should use the designation a), b) and c).

12. Claim 25 is objected to because "An isolated" should read -- The isolated -- in referring to claim 1, also "of" should be inserted after "sequence" at line 2.

Claim Rejections - 35 USC § 112

13. Claims 1-16 rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims an isolated DNA sequence encoding barley HPPD and methods of using same.

Applicant describes an isolated DNA encoding a barley HPPD enzyme having the amino acid sequence of SEQ ID NO: 2.

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Applicant does not describe the genus of DNAs encoding barley HPPD.

Hence, it is unclear that Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. In the instant case, the limitation "barley HPPD" does not limit the claimed DNA because "barley" is recognized by the art to encompass many species within the plant genus *Hordeum*.

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description

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purposes, even when accompanied by a method of obtaining the claimed sequence. In the instant case, Applicant has only described a single species.

14. Claims 1-16 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated DNA encoding the amino acid sequence of SEQ ID NO: 2 and methods of using it and plants transformed therewith, does not reasonably provide enablement for an isolated DNA encoding any barley HPPD. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims an isolated DNA sequence encoding barley HPPD and methods of using same.

Applicant teaches an isolated DNA encoding a barley HPPD enzyme having the amino acid sequence of SEQ ID NO: 2.

Applicant does not teach the genus of DNAs encoding barley HPPD.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

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The instant claims are directed to any isolated DNA encoding barley HPPD.

Applicant teaches only one species of the claimed genus of DNAs. Applicant provides no guidance on how to make and use other species within the claimed genus, and does not provide any guidance on how to make and use modifications or variants of the claimed genus of isolated DNAs as broadly claimed. The art teaches that ultimately the function of any DNA sequence, whose identity is based solely on homology, can only be proven by experiments designed to evaluate that function (Duggleby 1997, Gene 190:245-249, see page 248, left column, last paragraph). The art teaches that making an assertion of function based on sequence similarity and conserved regions does not necessarily teach that function (see Trentmann and Kende 1995, Plant Molecular Biology 29:161-166, see page 165, left column, 1st paragraph). In the instant case, the limitation "barley HPPD" does not limit the claimed DNA because "barley" is recognized by the art to encompass many species within the plant genus *Hordeum*. Hence, given Applicant's limited guidance, the breadth of the claims and the teachings of the art it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to isolated and identity the broad genus of DNAs encoding barley HPPD as broadly claimed.

See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that,

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once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.”.

15. Claim 8 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 8, 2), the limitation “the recombinant clones” lacks proper antecedent basis within the claim. Appropriate correction is required.

Conclusion

16. This Office action is non-final because it puts forth new grounds of rejection not previously presented.

17. The claims are free of the prior art, which neither teaches nor fairly suggests an isolated DNA encoding barley HPPD.

18. Claims 1-16 are rejected.


19. Claim 25 is objected to.

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20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.


DAVID H. KRUSE, PH.D.
PATENT EXAMINER

David H. Kruse, Ph.D.
6 October 2004

21. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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